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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,807	11/30/2001	Jay Short	DVSA-1005US	6627

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/997,807

Applicant(s)

SHORT ET AL.

Examiner

Michael Borin

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,34,35,114,115,132-154 and 189-215 is/are pending in the application.
- 4a) Of the above claim(s) 35,132,133,136-139,201 and 207-213 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,34,35,114,115,132-154,189-200, 202-206,214 and 215 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>04/13/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 31,34,35,114,115,132-154,189-215 are pending.

In response to restriction requirement filed 10/06/2006, applicant elected Group I, claims 31,34,35,114,115,132-154,189-200, 202-206, 214, 215, without traverse. Claims 201,207-213 are withdrawn from consideration as drawn to non-elected groups. In addition, claims 35,132,133,136-139 remain withdrawn from consideration as drawn to non-elected species.

Claims 31,34,114,115,134,140-154,189-200,202-206, 214, 215 are addressed to the extent they are drawn to the elected species, peptide SEQ ID No. 2, as peptide species, and self-assembly, as the way of polymerizing.

Information Disclosure Statement

With regard to the information disclosure statement filed 04/13/2005, as applicant now provided a concise explanation of the relevance of the German-language references listed therein, the IDS is considered acceptable. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34,114,115,134,140-154,189-200,202-206, 214, 215 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

A. Claims 31, and new added claims: The term "non-monomeric polypeptide" is not clear. As any polypeptide is not a "monomer" it is not clear how "non-monomeric polypeptide" is being defined. The specification, although providing particular examples, does not provide a standard for ascertaining the requisite composition, and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.

B. Claim 202: The claim addresses conjugates wherein non-monomeric polypeptide further comprises enzyme, antibody, etc. It is not clear, further to what other structure non-monomeric polypeptide comprises such elements.

C. Claim 205: The claims is unclear, the base claim requires presence of the non-monomeric polypeptide at the time of polymerization: the step "polymerizing" addresses monomeric polypeptide, and the proviso "at least one..." adds that at least one monomeric polypeptide has an attachment, thus the attachment is present at the time of polymerization.

D. Claim 215: It is not clear whether the non-monomeric polypeptide is attached to "plurality of monomeric peptides" at once or separately.

Claim Rejections - 35 USC 112, first paragraph (new matter).

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31,34,114,115,134,140-154,189-206, 214, 215 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 31 (and new added claims) introduces new matter as it claims now that monomeric polypeptides comprise attachment of a non-monomeric polypeptide. Although applicant points at sections of Pre-grant publication 20030198681 as providing sufficient support, paragraphs 0294, 0363, 0364 do not address the genus of non-monomeric polypeptides as now claimed.

Claim Rejections - 35 USC 112, first paragraph (enablement).

Claims 31,34,114,115,134,140-154,189-201 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for self-assembly of peptide SEQ ID No. 2 itself or its conjugate with green fluorescent protein, does not reasonably provide enablement for self-assembly of a peptide SEQ ID No. 2 modified by an attachment and/or by substitution of its residues.

The claims are drawn to producing polymers by self-assembly of peptide SEQ ID No.2 having attachment of a "non-monomeric polypeptide". Thus, the claims as amended are drawn to producing polymers by self assembly of fusion proteins comprising SEQ ID No.2. Even though self-assembly of peptide SEQ ID No. 2 is demonstrated in the specification, it does not reasonably provide enablement for polymers formed from conjugates of said monomeric polypeptide with other "non-monomeric polypeptide". It is well known that process of self-assembly of polypeptide monomers into polymers depends critically on the structure of the monomers and even slight changes, such as change in length of chain, or addition of ionized residue may change the rate and/or direction of the reaction. See, for example, Urry et al., or Jenekhe et al. Urry et al discusses that, depending on the structure of the peptide monomer, it can either self-assemble or separate (de-mix). See p. 420. Jenekhe et al. teach that, although many synthetic polymers can organize into segregated mesophases, they might lack rigid sequences and well defined intermolecular interactions¹. See abstract. Other than general assertions in the specification, there are no examples in specification of self-assembly of any single polypeptide having an "non-monomeric polypeptide" attachment such as large proteins, antibodies, enzymes, etc. Much less is there support for self assembly of derivatized peptide SEQ ID No. 2 into such structured polymer formation as peptide tubes or nanoscale delivery vehicles, e.g., nanocages.

¹ i.e., even though some polypeptides can organize into segregated mesophases, they are not forming polymers (as claimed) but form mesophases lacking polymerized sequences.

The Declaration of Dr. Barton providing an example of polymerization of conjugate of Green Fluorescent Protein with polypeptide SEQ ID No. 2 is not sufficient as it does not commensurate with the scope of the invention as claimed².

In view of the above, it is the Examiners position that with the insufficient guidance and working examples and in view of unpredictability and the state of art one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

Response to arguments

Applicant argues that the method should be considered enabled for at least the embodiments wherein the attachment of "non-monomeric polypeptide" is done after the polymerization. Examiner disagrees. In claim 31, the step "polymerizing" addresses monomeric polypeptide, and the proviso "at least one..." adds that at least one monomeric polypeptide has an attachment, thus the attachment is present at the time of polymerization. Thus, the method as claimed does require the attachment to the monomeric polypeptide to exist before the polymerization.

Applicant further argues that because the claims do not require attachment present on every monomer, it would be reasonable to conclude that the presence of "only one or few conjugated monomers in a batch" could polymerize as effectively as a system comprising only unconjugated monomers. Examiner disagrees. The arguments of counsel can not take the place of evidence in the record.

² Even though the examination at this point is limited to the elected species, i.e., polypeptide SEQ ID No. 2, it should be noted that there is no examples of self-assembly of other polypeptide species of the invention.

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With respect to the Declaration of Dr. Barton, Examiner agrees that the Declaration sufficiently describes polyperization of monomeric polypeptide of SEQ ID No. 2 having attachment of Green Fluorescent Protein., However, this showing does nor commensurate with the scope of invention as claimed (see discussion in the revised rejection above). The scope of the showing must be commensurate with the scope of claims to consider. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claims.

With respect to the use of the term "Pyrotex", even though the issue is moot at the point as the claims no longer address conjugates with lipids, Examiner notes that neither Figs. 3A,B, nor the attached California State Science Fair (post-filing document) identify "Pyrotex" as being a polymer of peptide SEQ ID No. 2.

Conclusion.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MICHAEL BORIN, PH.D.
PRIMARY EXAMINER

Michael Borin, Ph.D.
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Art Unit 1631

mlb

